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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/526,348	03/16/2000	Dr. Guido Bojack	514413-3817	2532

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EXAMINER

CRANE, LAWRENCE E

ART UNIT	PAPER NUMBER
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1623

DATE MAILED: 09/23/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/526,348

Applicant(s)

BOJACK ET AL.

Examiner

L. E. Crane

Art Unit

1623

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 15 July 2005.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-3 and 5-17 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-3 and 5-17 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☒ All b) ☐ Some * c) ☐ None of:
1. ☒ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date _____.
- 4) ☐ Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____.
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: _____.

No additional claims have been cancelled, claims **1, 3, 5, 7-9 and 11** have been amended, the abstract has not been further amended, the disclosure has not been amended, and no new claims have been added as per the amendment filed July 15, 2005. No additional Information Disclosure Statements (IDSs) have been received.

Claims **1-3 and 5-17** remain in the case.

Note to applicant: when a rejection refers to a claim X at line y, the line number "y" is determined from the claim as previously submitted by applicant in the most recent response including ~~lines deleted by line through~~.

Claims **1-3 and 5-17** are rejected under 35 U.S.C. §112, first paragraph, as containing subject matter which was not described in the specification in such a way as to enable one of ordinary skill in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention.

The fundamental issue here is whether practicing the full scope of the instant invention is possible without undue experimentation. As provided for in *In re Wands* (858 F.2d 731, 737; 8 USPQ 2d 1400, 1404 (Fed Cir. 1988) the minimum factors to be considered in determination of whether a conclusion of "undue experimentation" is appropriate are as follows.

A. The breadth of the claims is excessive in view of the number of specific embodiments listed in the Tables at pages 63-123 (11 examples) when compared with the total number of examples (a total of 698 separate examples are listed at pages 63-123).

B. The nature of the invention is compounds which are adenosine deaminase (ADA) inhibitors and/or adenosine monophosphate deaminase (AMPDA) inhibitors and their administration to plants as a herbicide, but without any guidance concerning which disease conditions are to be treated and how such treatment should proceed, or what other plant growth is to be inhibited.

C. The state of the prior art varies widely, but in some cases is very limited because the synthesis of several of the bicyclic heterocycles is presently unknown in the prior art.

D. The level of one of ordinary skill also varies widely because of the wide variation in the amount of prior art available in either the synthetic or medicinal areas depending on the ring system selected.

E. The level of predictability in the art also varies widely because of the lack of information concerning how to make or use several of the heterocyclic systems included within the scope of the claims.

F. The amount of direction provided by the inventor is quite limited because the number of examples provided (only 11 compounds characterized), wherein only a subset were tested for biological activity, and none of these tests for biological activity were conducted on whole mammalian hosts (all *in vitro* tests) and no tests were conducted on any plants.

G. The existence of working examples is very limited with only 11 compounds prepared and characterized and only 5 tested for ADA activity using rabbit ADA.

H. The quantity of experimentation needed to make or use the invention based on the content of the disclosure would be very substantial because of the lack of prior art teachings to guide the synthetic efforts where the bicyclic heterocycles are previously unknown and the almost complete absence of medicinal test data to guide experimentation concerning how best to effect ADA inhibition in a complete mammalian hosts. Examiner therefore concludes that, in the absence of considerably larger quantities of both synthetic and medicinal testing data, the instant claimed subject matter could only be practiced following expenditure of an undue amount of experimentation in both the synthetic and medicinal testing areas. In addition, the vast array of substituents, nested substituents, and inoperative embodiments like SF₅ (claim 1 at line 19, claim 2 at line 5, claim 4 at line 23, etc.; a very hydrolytically unstable substituent at best) make the task of the ordinary practitioner attempting to practice the instant invention even more difficult.

Applicant's arguments filed July 15, 2005 have been fully considered but they are not deemed to be persuasive.

Applicant at pages 31-32 of the response argues that the scope of the compounds being claimed is reasonable. Examiner respectfully disagrees, noting for example that there appear to be no examples in the extensive tables wherein there is a sulfur ring heteroatom provided for,

and no examples of the synthesis of such mercapto, sulfoxyl or sulfone containing compounds appear to have been disclosed.

And at page 33 applicant argues that "... the inhibition of AMPDA and ADA enzymes in plants by instant compounds of formula (I) has never been shown previously, but is clearly demonstrated by biological examples of the instant application." Examiner finds this to be an incorrect statement in light of the test data provided which appears to be limited to *in vitro* tests of compounds for activity against rabbit (mammalian) ADA. Examiner has reviewed the disclosure and has not found any test results wherein any plants or plant tissue samples have been tested.

Examiner suggests limitation of the scope of the instant claims to much more nearly correspond to the very limited scope of the specific exemplifications. Examiner finds minimal support within the instant specific embodiments for the vast arrays of substituent group laundry lists directed to the definitions of variable substituents, including obviously inoperative groups like "SF₅." Examiner also finds the minimal descriptions of the particular chemical process steps to be entirely inadequate because there is insufficiently detailed instruction in the process claims directed to how the process steps are carried out, including failure to provide for a clear disclosure of the actual reagents required; e.g. "chlorinating agent" includes a substantial array of possible reagents many of which are inappropriate for the claimed process.

Claims 1-3 and 5-17 are rejected under 35 U.S.C. §112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 1 is apparently directed to a method of treating and therefore is incomplete for failure to specify any specific disease condition(s) being treated by said administration.

Applicant's arguments with respect to claim 1 have been considered but are deemed to be moot in view of the new grounds of rejection necessitated by applicant's amendments.

In claim 1 at lines 54-55 (formerly lines 62-64), the variable "L" is defined as "attached cyclically to the bridge G ... via a hetero atom selected from the group consisting of O and S," a term which incompletely describes what is being claimed because the particular structures being referred to are not provided.

Applicant's arguments filed July 15, 2005 have been fully considered but they are not deemed to be persuasive.

Examiner notes the deletion of the variable defined as "N" but does not see any additional amendment to address the functional nature of the definition. Examiner suggests that introduction of a structural representation(s) is(are) necessary to properly address this rejection.

In claim 1 at lines 73-74 (previously lines 69-70), the terms "aryl" and "heterocyclyl" are incompletely defined for lack of an upper size limit or a specification of the nature and location of hetero atoms. See also the terms "substituted aryl," "heteroaryl," and "substituted heteroaryl" originally at lines 78-79 and see also dependent claims.

Applicant's arguments filed July 15, 2005 have been fully considered but they are not deemed to be persuasive.

Applicant has not responded to this particular rejection.

In claim 8 at line 8, the term "Z is a precursor of the radical G-L" is incomplete because this functional description fails to describe what the structure of "Z" is. See also claims 9 and 11.

Applicant's arguments filed July 15, 2005 have been fully considered but they are not deemed to be persuasive.

Applicant is respectfully requested to amend the instant claim by introduction of the relevant portions of the subject matter noted by applicant to be present at page 30 of the disclosure into said claim.

Claim 8 is incomplete because the term "modifying" at line 11 implies a chemical process step but fails to completely describe the process step implied. See also claim 9 at line 8 wherein the term "cyclizing" has the same problem. See also claim 11 ("condensing" and "cyclizing").

Applicant's arguments filed July 15, 2005 have been fully considered but they are not deemed to be persuasive.

Applicant argues in effect that a more complete definition of the noted terms is not required in the claims. Examiner respectfully disagrees and emphasizes that a more complete definition of the process steps being claimed is necessary for the claim to be complete and to have properly defined metes and bounds. The following response from the previous office action has been repeated to emphasize the need to make major changes.

Applicant's arguments filed October 25, 2004 have been fully considered but they are not deemed to be persuasive.

Applicant asserts that "... the term 'modifying' and the like ... such as 'cyclizing,' [are] specific modification steps ... known to a person skilled in the art of chemistry and are not a specific contribution according to the invention which .. is in the structure of the final product." Examiner respectfully disagrees. The claim does not set forth any step(s) involved in the method/process, and therefore it is unclear what method/process applicant is intending to encompass. A claim is indefinite where it merely recites a process step without any active, positive steps delimiting how this use is actually practiced. And in addition, because of the lack of specific and complete structural information concerning starting material, product and reagents in the noted claim, it is presently impossible to determine which bonds are formed and/or broken during the claimed "cyclizing," "modifying," "reducing," or other step(s) being claimed herein. As to applicant assertion that the chemical structure is essentially the only contribution, the instant "claimed" chemical process steps are clearly also part of applicant's "specific contribution." And lastly, applicant appears to be using the noted terms ("cyclizing" and the like) in a manner similar to the term "utilizing" (MPEP §2173.05(q)), the noted terms therefore appear to be objectionable in view of *Ex parte Porter* (25 USPQ2d 1144 (Bd. Pat. App. Inter. 1992)).

For these reasons, examiner concludes that the metes and bounds of the claimed subject matter have not been adequately established.

Claim 7 is rejected under 35 U.S.C. §112, fourth paragraph, as being of improper dependent form for failing to further limit the subject matter of a previous claim.

Claim 7 is not properly dependent from claimed directed to method of treatment claims or method of making claims and therefore each of said claims fails to limit the subject matter of the claim dependent from. Applicant is respectfully requested to incorporate all of the

appropriate definitions of variables into the noted claims and to remove the incorrect dependencies from each of said claims. Additional fees for independent claims may be due to the PTO following these amendments.

Applicant's arguments filed July 15, 2005 have been fully considered but they are not deemed to be persuasive.

Examiner notes the major amendment of claim 7 with appreciation, but wonders why claim 7 still includes the term "as defined in claim 1" three lines from the end, a term which now appears to be superfluous. Clarification is respectfully requested.

Claim 1 is objected to because of the following informalities:

In claim 1 at line 9, the term "is a nitrogen atom" appears twice and appears by the context to be a typographical error in the second occurrence. See also claim 7 at line 7.

In claim 3 at the next to last line, the term "from the" appears to be superfluous and therefore its deletion is respectfully requested to permit the line to be grammatically correct. In addition the last line appears to be superfluous as well so its deletion also appears to be appropriate. Clarification is respectfully requested.

Claim 11 lacks terminal punctuation.

In claim 15 at line 2, the term "using" is technically incorrect and should be replaced by the term -- administering --.

Claim 16 at line 3, the term "the growth in corps of useful or ornamental plants" appears to contain at least one spelling error and one error in usage. Did applicant intend the term to read
-- the growth in crops of economically important plants or of ornamental plants -- .

Appropriate correction is required.

Claims 1-3 and 5-17 would be allowable if rewritten or amended to overcome the rejection under 35 U.S.C. §112.

Applicant's amendment necessitated the new grounds of rejection. Accordingly, **THIS ACTION IS MADE FINAL**. Applicant is reminded of the extension of time policy as set forth in 37 C.F.R. §1.136(a).

A shortened statutory period for response to this final action is set to expire **THREE MONTHS** from the date of this action. In the event a first response is filed within **TWO MONTHS** of the mailing date of this final action and the advisory action is not mailed until after the end of the **THREE-MONTH** shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 C.F.R. §1.136(a) will be calculated from the mailing date of the advisory action. In no event will the statutory period for response expire later than **SIX MONTHS** from the date of this final action.

Papers related to this application may be submitted to Group 1600 via facsimile transmission (FAX). The transmission of such papers must conform with the notice published in the Official Gazette (1096 OG 30, November 15, 1989). The telephone number to FAX (unofficially) directly to Examiner's computer is 571-273-0651. The telephone number for sending an Official FAX to the PTO is 703-872-9306.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Examiner L. E. Crane whose telephone number is **571-272-0651**. The examiner can normally be reached between 9:30 AM and 5:00 PM, Monday through Friday.

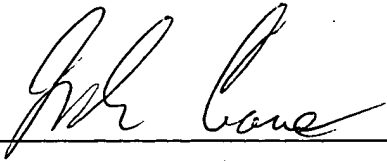
If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Mr. James O. Wilson, can be reached at **571-272-0661**.

Any inquiry of a general nature or relating to the status of this application should be directed to the Group 1600 receptionist whose telephone number is **571-272-1600**.

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LECrane:lec
09/19/2005

A handwritten signature in cursive script, appearing to read "L. E. Crane", is written over a horizontal line.

L. E. Crane, Ph.D., Esq.
Primary Patent Examiner
Technology Center 1600